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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/065,279 | 09/30/2002 | Jeffrey C. Leung | 013341.000020 | 5693 |

24239 7590 09/04/2007

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| EXAMINER | |
|---|---|
| NGUYEN, TUAN VAN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/04/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/065,279 | LEUNG ET AL. | |
| | Examiner | Art Unit | |
| | Tuan V. Nguyen | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *March 22, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-58,60 and 63-140* is/are pending in the application.

4a) Of the above claim(s) *37-57,59,61,62, and 63-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36,58,60, and 102-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003 and 16 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

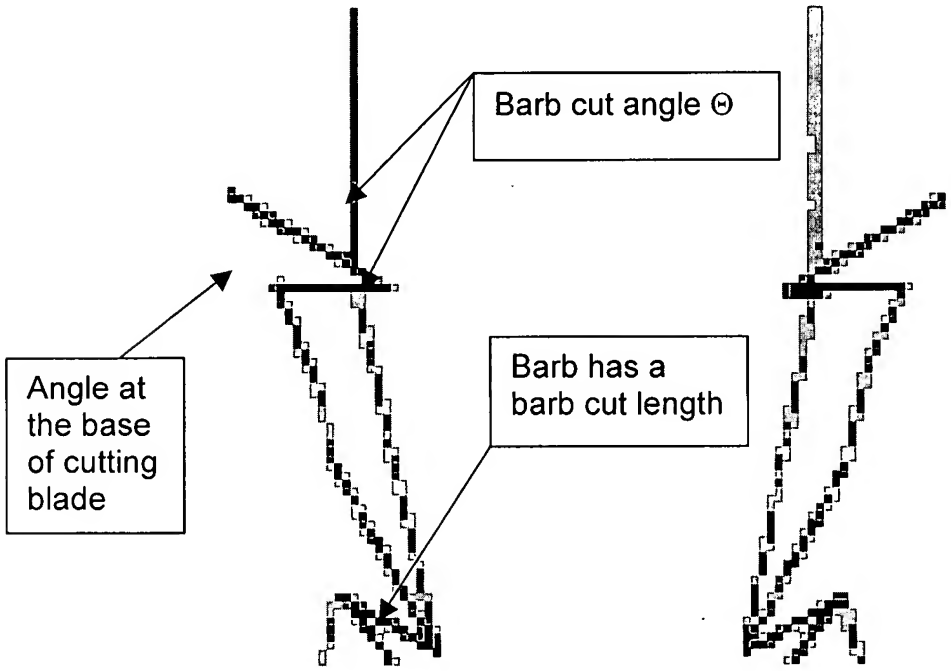
## DETAILED ACTION

### *Response to Amendment*

1. Applicant's arguments filed on March 22, 2007 with respect to claims 1-3, 5-9, 10-12, 14-18, 19-21, 28-30, 32-36 and 58 have been fully considered but they are not persuasive. .

2. With respect to arguments regarding Buncke reference does not teach or suggest barb cut angle Θ and without any additional guidance, therefore the Buncke reference is not sufficient to meet the Office's burden of establishing a *prima facie* case of obviousness. Examiner respectfully traverses the applicant's remarks: in Figure 15 of Buncke reference discloses method for forming a barbed suture 88a from suture filament material 88 by using rotating cutting wheels 90 wherein the cutting wheels have cutting blades located radially on the outer periphery of the wheel. What is abundantly clear from the Figure 15 of Buncke drawings is that the cutting blade has a sharp cutting edge, a base and an angle (see Figure below this paragraph) whereby, said angle of the cutting blade creates the barb cut angle Θ on the suture (see Figure below this paragraph). The Figure below this paragraph is a copy of Fig. 15 from Buncke reference clearly shown the barb cut angle Θ, definitely, ranging from about greater than 0 degree to less than 180 degree, possibly, ranging from about 135 degree to less than 180 degree. Here it is noted that It has been held that things clearly shown in reference patent drawing qualify as prior art features, even though unexplained by the specification. In re Mraz, 173

USPQ 25 (CCPA 1972). Futhermore, it would have been an obvious to a person of ordinary skill in art to derive the optimum range of the barb cut angle Θ, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention was made by the applicant to use have a barb cut angle ranging from about 140 degrees to about 175 degrees, because applicant has not disclosed that this range provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Buncke suture, and applicant's invention, to perform equally well.



3. With respect to arguments regarding Buncke reference does not teach or suggest a ratio of any type and the disclosure is completely devoid of any mention of a ratio of barb cut length to the suture diameter and barb cut depth to the suture diameter. Examiner respectfully traverses the applicant's remarks: Buncke discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barb spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines12-19) and furthermore, Buncke clearly discloses in Figure 15 the barb cut length and barb cut depth are created by the cutting blade on wheel 90 (see Figure below paragraph 5). Definition of the word "ratio" according to the Merriam-Webster's Collegiate Dictionary, Tenth Edition principal copyright 1993, page 969, is *the indicated quotient of two mathematical expressions* or *the relationship in quantity, amount, or size between two or more things*. Here it is noted that applicant fails to disclose the advantage or purpose of the ratio of barb cut length to the suture diameter and the ratio of barb cut depth to the suture diameter. Buncke already discloses the suture diameter and the barb cut length and Buncke indicates that the depth of the barb depending, to a large extent, on the diameter of the suture material (see col. 8, lines 10-20), therefore, it would have been an obvious to a person of ordinary skill in art to describe the characteristic of the barb on the suture by using the ratio of barb cut length to the suture diameter involves only routine skill in the art.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-3, 5-9, 0-12, 14-18, 19-21, 23-27, 28-30, 32-36, and 58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buncke (U.S. 5,931,855).**

6. Referring to **claims 1-3 and 9**, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines12-19). Buncke reference fails to disclose the barb cut angle ranging from about 140 degrees to about 175 degrees, however, what is abundantly clear from the Figure 15 of Buncke drawings is that the cutting blade has a sharp cutting edge, a base and an angle (see Figure below paragraph 5) whereby, said angle of the cutting blade creates the barb cut angle $\Theta$ on the suture (see Figure below paragraph 5). The Figure below paragraph 5 is a copy of Fig. 15 from Buncke reference clearly shows the barb cut angle $\Theta$, definitely, ranging from about greater than 0 degree to less than 180 degree, possibly, ranging from about

135 degree to less than 180 degree. Therefore, it would have been an obvious to a person of ordinary skill in art to derive the barb cut angle from the depth and spacings parameters given by Buncke, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention was made by the applicant to use have a barb cut angle ranging from about 140 degrees to about 175 degrees, because applicant has not disclosed that the umbrella structure shape provides an advantage, is used for a particular purpose, or solves a stated problem.

7. Referring to **claims 5-8**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).

8. Referring to **claims 10-12 and 18**, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines12-19).

9. Referring to **claims 14-17**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).

10. Referring to **claims 19-22 and 27**, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the barbs spacings can be from about 100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines12-19). Buncke reference fails to disclose the barb cut length and the ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2. Here it is noted that Buncke disclose the spacings between barbs therefore the barb cut length is felt into this range. Furthermore, Buncke clearly discloses in Figure 15 the barb cut length is created by the cutting blade on wheel 90 (see Figure below paragraph 5). Definition of the word "ratio" according to the Merriam-Webster's Collegiate Dictionary, Tenth Edition principal copyright 1993, page 969, is *the indicated quotient of two mathematical expressions* or *the relationship in quantity, amount, or size between two or more things.* Here it is noted that applicant fails to disclose the advantage or purpose of the ratio of barb cut length to the suture diameter. Buncke already discloses the suture diameter and the barb cut length and Buncke indicates that the depth of the barb depending, to a large extent, on the diameter of the suture material (see col. 8, lines 10-20), therefore, it would have been an obvious to a person of ordinary skill

in art to describe the characteristic of the barb on the suture by using the ratio of barb cut length to the suture diameter involves only routine skill in the art.

11. Still referring to **claims 19-22 and 27,** it would have been an obvious to a person of ordinary skill in art to derive the ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2 from the spacings and barb cut depth parameters given by Buncke, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention was made by the applicant to use have a ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2, because applicant has not disclosed that this ratio expression provides an advantage, is used for a particular purpose, or solves a stated problem.

12. Referring to **claims 23-26**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).

13. Referring to **claims 28-30 and 36**, Buncke discloses (see Figure 2) a barbed suture having a staggered disposition. Further, the barbs are all facing in a direction to the first and second end (see col. 9, lines 4-7). Buncke further discloses the suture 84 has a small diameter which may be in the range of about 100 to 500 microns, the barb cut distance or barbs spacings can be from about

100 microns to about 1 mm, and the depth of the barbs formed in the suture material can be about 30 microns to 100 micron (see col. 8, lines12-19).

14. Referring to **claims 32-35**, Buncke discloses the suture can be nonabsorbable such as polyester or bioabsorbable material such as polymers and copolymers of glycolic and lactic acid (see col. 1, lines 20-25).

15. Referring to **claim 58**, it is rejected for the same reason as claim 1 combined with 10, 19, and 28.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. **Claims 4, 13, 22, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and further in view of Buncke (U.S. 5,931,855).**

19. Referring to **claims 4, 13, 22, and 31**, Buncke discloses the invention substantially as claimed except for each set having a barb size different from the barb size of the other set. It would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to made one set of barb having a barb size different from the barb size of the other set because Applicant has not disclosed that this particular design provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Buncke, and applicant's invention, to perform equally well. Furthermore, A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, it has been hold that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 225 USPQ 232 (1984).

20. **Claims 115-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (U.S. 5,931,855) and further in view of Ruff (U.S. 5,342,376).**

21. Referring to claims 115-140, Buncke discloses the invention substantially as claimed except for the cross section of suture body has a circular or non-circular cross section. Ruff discloses a barb suture having the cross section of suture body has a circular or non-circular cross section (see Figs. 7 and 9 and col. 6, lines 5-23). Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to made the suture body having a circular or non-circular cross section because Applicant has not disclosed that the suture body with a circular or non-circular cross section provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Ruff or Buncke, and applicant's invention, to perform equally well.

***Double Patenting***

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.

Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claim 58 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 22 of copending Application No. 10/065280 (Pub. No. US 2004/0060410). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially claimed the same invention.

24. Claim 60 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of copending Application No. 10/065280. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially claimed the same invention.

25. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
August 10, 2007

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
8/16/07